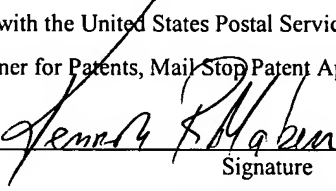


ATTORNEY DOCKET NUMBER: 2004117-0008 (NEMC 197-DIV)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Carr, <i>et al.</i>	Examiner:	TBA
Serial No.:	TBA	Group Art Unit:	TBA
Filed:	April 21, 2004		
For:	NOVEL CHIMERIC ANALGESIC PEPTIDES		

Mail Stop: Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Certificate of Mailing	
I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Mail Stop Patent Application, P.O. Box 1450, Alexandria, VA 22313-1450	
April 21, 2004 Date	 Signature
	Kenneth R. Maben Typed or Printed Name of person signing certificate

Sir:

STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☒ An *original* Information Disclosure Statement; or
- ☐ A *supplemental* Information Disclosure Statement.

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
- ☒ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
 - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
 - ☐ Before the mailing of a first Office action on the merits; or
 - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
- ☐ Certifies that *either*:
 - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
 - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☒ A copy of each cited reference not indicated with a check mark (✓) is included;
- ☒ Copies of references indicated with a check mark (✓) on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status
09/428,692	October 28, 1999	Allowed

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☐ Does not contain non-English language citations;
- ☐ Does contain non-English language citations, of which the following is a concise

explanation:

[] Includes one or more translations of a non-English citation.

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).

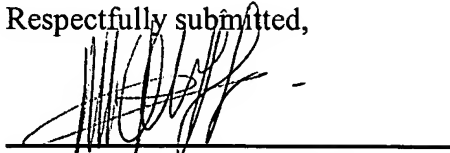
The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,



Nadège M. Lagneau, Ph.D.
Agent for Applicant
Reg. No. 51,908

Dated: April 21, 2004

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Form PTO-1449
(REV. 8-83)

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket:
2004117-0008
(NEMC 197-DIV)

In re Application No.
TBA

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant: Carr *et al.*

Filing Date:
April 21, 2004

Group: TBA

U. S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	✓ 5,891,842	Kream	04/06/99		

U. S. PATENT APPLICATIONS

	Document No.	Applicant	Filing Date		

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	Publication Date	Translation	
				Yes	No

Examiner's
Initials

OTHER DOCUMENTS
(Including Author, Title, Date, Pertinent Pages, Etc.)

	✓ Carr et al., "Neural Blockade in Clinical Anesthesia and Management of Pain", Third ed., pp. 915-983, 1998.
	✓ Foran et al., "Inhibition of Morphine Tolerance Development by a Substance P-Opioid Peptide chimera", <i>J. Pharmacol. Exp. Ther.</i> , 295 (3): 1142-1148, 2000.
	✓ Foran et al., "A substance P-opioid chimeric peptide as a unique nontolerance-forming analgesic", <i>Proc. Natl. Acad. Sci.</i> , 97 : 7621-7626, 2000.
	✓ Foran et al., "Chimeric peptide for the treatment of acute and chronic pain", Anesthesiology (Hagerstown), Vol. 91, No. 3A, 1999, p. A944 XP000996135 Annual Meeting of the American Society of Anesthesiologists; Dallas, Texas, USA; October 9-13, 1999 ISSN: 0003-3022.

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| | ✓ Foran S., "Characterization of Novel Chimeric Analgesic Peptides", Ph.D. Dissertation, Tufts University, Sackler School of Graduate Biomedical Sciences, September 2000. |
| | ✓ Hyden et al., <i>Eur. J. Pharmacol.</i> , 86 :95-98, 1983. |
| | ✓ Hyden et al., <i>J. Pharmacol. Exp. Ther.</i> , 226 :398-404, 1983. |
| | ✓ Kream et al., <i>Proc. Nat'l. Acad. Sci. USA</i> , 90 :3564-3568, 1993. |
| | ✓ Langel et al., "Design of chimeric peptide ligands to galanin receptors and substance P receptors", <i>International Journal of peptide and protein research</i> , DK, Munksgaard, Copenhagen, 39 (6): 516-522, 1992. |
| | ✓ Lei <i>et al.</i> , "Opioid and neurokinin activities of substance P fragments and their analogs", <i>Eur. J. Pharmacol.</i> , 193 (2):209-215, 1991. |
| | ✓ Lipkowski et al., "Neuropeptides: Peptide and Nonpeptide Analogs", Gutte ed., Academic Press pp 287-320, 1995. |
| | ✓ Lipkowski et al., "An approach to the self regulatory mechanism of substance P actions: II. Biological activity of new synthetic peptide analogs related both to enkephalin and substance P", <i>Life Sciences</i> , 33 (Sup. I): 141-144, 1983. |
| | ✓ Lipkowski et al., "Opioid Peptide Analogues: Reconsideration as a Potentially New Generation of Analgesics", <i>Polish J. Chem.</i> , 68 : 907-912, 1994. |
| | ✓ Lipkowski <i>et al.</i> , "Peptides as receptor selectivity modulators of opiate pharmacophores", <i>J. Med. Chem.</i> , 29 : 1222-1225, 1986. |
| | ✓ Lipkowski <i>et al.</i> , "Benzomorphan alkaloids, natural peptidomimetics of opioid peptide pharmacophores", <i>Lett. Peptide Res.</i> , 2 : 177-181, 1995. |
| | ✓ Lipkowski <i>et al.</i> , "Biological activities of a peptide containing both casomorphin-like and substance P antagonist structural characteristics", in <i>Casomorphins and related peptides. Recent developments</i> , V. Brantl, H. Teschemacher, eds, VCH, Weinheim, pp. 113-118, 1994. |
| | ✓ Maszczyńska et al., "Dual functional interactions of Substance P and opioids in nociceptive transmission: Review and Reconciliation", <i>Analgesia</i> , 3 :259-268, 1998. |
| | ✓ Maszczyńska et al., "Alternative forms of interaction of substance P and opioids in nociceptive transmission", <i>Letters in Peptide Science</i> , 5 : 395-398, 1998. |
| | ✓ Misterek et al., "Spinal co-administration of peptide substance P antagonist increases antinociceptive effect of the opioid peptide biphalin", <i>Life Sciences</i> , 54 (14): 939-944, 1994. |
| | ✓ Patent Abstracts of Japan, Vol. 1999, No. 8, 30 June 1999 & JP 11060598 A (ASASHI |

Form PTO-1449
(REV. 8-83)

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GLASS CO LTD), 2 March 1999 abstract, page 3, Formula 1(A).

✓ Schiller et al., *J. Med. Chem.*, 36:3182-3187, 1993.

✓ Silbert et al., "Analgesic activity of a novel bivalent opioid peptide compared to morphine via different routes of administration", *Agents and Action*, 33:382-387, 1991.

✓ Silbert et al., *Prog. Clin. Biol.*, 328:485-488, 1990.

✓ Sizheng et al., "Opioid and neurokinin activities of substance P fragments and their analogs", *Eur. J. Pharmacology*, 193: 209-215, 1991.

✓ Ward et al., *J. Med. Chem.*, 33:1848-1851, 1990.

✓ Zadina et al., *Life Sci.*, 55:461-466, 1994.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.